Southwestern Health Resources



UTSouthwestern Medical Centers

COVID 19 PHARMACY UPDATE May 7, 2020

Disclaimer: We are getting frequent COVID-related questions about drug concerns and potential interactions. This information is as May 7, 2020. We will do our best to keep you up to date with this ever evolving situation. This is the most update information at the time of publication.

Note: There are no Food and Drug Administration (FDA) approved therapies for treatment or prevention of COVID-19. If at all possible, it is best to have patients enrolled in a clinical trial.

STATINS AND COVID-19

The evidence is lacking for the use of statins for treatment of COVID-19. However, it is recommended for patients already on statin therapy for treatment or prevention of cardiovascular disease to continue taking as prescribed¹.

Statins have the following proposed mechanisms to help in respiratory illnesses. They have anti-inflammatory and immunomodulatory effects that may prevent acute lung injury by controlling the host response to COVID-19 ². Statins also affect ACE2 which reduces endothelial dysfunction and plays a role in acute respiratory distress syndrome (ARDS)³. Some observational studies in other respiratory illness, including pneumonia and influenza, reported that statins may reduce cardiovascular outcomes ⁴. However, these are only observational studies. There are no large scale randomized trials.

There are ongoing clinical trials that are evaluating the effectiveness of statin in the treatment of COVID-19. NIH COVID-19 treatment guidelines recommend for patients on a statin for prevention or treatment of cardiovascular disease to continue their statin as prescribed. They also recommend against initiation of a statin for treatment of COVID-19 unless enrolled in clinical trial¹.

- National Institutes of Health. Coronavirus disease 2019 (COVID-19) treatment guidelines. From NIH website (https://covid19treatmentguidelines.nih.gov/concomitant-medications/) Accessed 2020 May 3.
- 2. Phadke M, Saunik S. COVID-19 treatment by repurposing drugs until the vaccine is in sight [published online ahead of print, 2020 Mar 29]. *Drug Dev Res.* 2020;10.1002/ddr.21666. doi:10.1002/ddr.21666
- 3. Fedson DS, Opal SM, Rordam OM. Hiding in Plain Sight: an Approach to Treating Patients with Severe COVID-19 Infection. mBio. 2020;11(2):e00398-20. Published 2020 Mar 20. doi:10.1128/mBio.00398-20
- 4. Is there a role for statin therapy in acute viral infections? From JACC website. https://www.acc.org/latest-in-cardiology/articles/2020/03/18/15/09/is-there-a-role-for-statin-therapy-in-acute-viral-infections-covid-19

COLCHICINE AND COVID-19

Colchicine is another existing medication that is now being investigated as a possible COVID-19 therapeutic option. Although the anticipated effect is promising, there is no evidence to support the use of colchicine in COVID-19 patients.

Colchicine, mainly used for treatment and prophylaxis of gout attacks, is noted for its anti-inflammatory properties. Several studies have also shed light on the potential cardioprotective effects of colchicine¹. Colchicine's mechanism of action includes interference with migration of neutrophils to sites of inflammation². In addition, colchicine blocks the inflammasome complex in neutrophils and monocytes, which mediate interleukin activation^{1,2}. It is hypothesized that this anti-inflammatory effect of colchicine will reduce the excessive inflammatory reaction caused by coronavirus that can lead to acute respiratory distress syndrome (ARDS), organ failure, and death³.

Currently, there are 6 clinical trials being conducted to evaluate if colchicine has any effect on hospitalized or outpatient COVID-19 patients⁴. Colchicine is well tolerated at low doses (< 3 mg/day), with common adverse effects mainly being GI disturbances (nausea, diarrhea, vomiting, etc.). However, more serious and dose-related (\ge 0.5 - 0.8 mg/kg) adverse effects include myelosuppression, myopathy, and neuropathy². Furthermore, contraindications include renal and/or hepatic impairment, as well as use in conjunction with P-glycoprotien (P-gp) and cytochrome P-450 3A4 (CYP3A4) inhibitors (i.e. clarithromycin, amiodarone, ritonavir, etc.), as this can lead to fatal colchicine toxicity².

- 1. <u>Deftereos S. Giannopoulos G. et al. "Colchicine as a potent anti-inflammatory treatment in COVID-19: can we teach an old dog new tricks?" European Heart Journal Cardiovascular Pharmacotherapy, https://academic.oup.com/ehjcvp/advance-article/doi/10.1093/ehjcvp/pvaa033/5825545. Accessed 4 May 2020.</u>
- 2. Colchicine. In: IBM Micromedex® DRUGDEX® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www-micromedexsolutions-com.ezproxy.ttuhsc.edu/(cited: *May 4, 2020*).
- 3. "Colchicine COVID-19 Trial Underway." *Physician's Weekly*, 1 April 2020, https://www.physiciansweekly.com/anti-inflammatory-drug-colchicine-on-deck-for-covid-19/. Accessed 4 May 2020.

REMDESIVIR - EMERGENCY USE

As of May 1, 2020, Remdesivir was granted approval by the FDA for emergency use within hospitalized adults and children with <u>severe</u> COVID-19, as defined by the FDA, outside of the boundaries of a clinical trial. Additional clinical trial data on remdesivir is still pending at this time. As with all potential treatments of COVID-19, it is best to enroll patients in clinical trial whenever possible.

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Potential Drug Shortages

The Health Plan of Southwestern Health Resources, Care N' Care has been monitoring potential drug shortages related to COVID-19 in outpatient settings. Care N' Care is able to gather data from up-to-the-minute pharmacy claims as well as information coming into the call centers from its members and pharmacies. The shortages are confirmed through the American Society of Health-System Pharmacists (ASHP) website. Please note, these are for outpatient drugs obtained in a retail setting only. There were no new drug shortages related to COVID-19 identified for the week of 4/29/2020 to 5/06/2020. The status for previously reported shortages are listed below:

- Flovent HFA and Flovent Diskus Inhalation Powder No Change. See Newsletter dated 4/22/2020
- Hydroxychloroquine/Chloroquine No change. See Newsletter dated 4/3/2020
- Hydrocortisone No change. See Newsletter dated <u>4/3/2020</u>

For additional information and updates on drug shortages please visit the American Society of Health-System Pharmacists <u>websites</u>.

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